UNIVERSIDADE DE LISBOA
FACULDADE DE CIÊNCIAS
DEPARTAMENTO DE FÍSICA

Development and Optimization of Low-Cost Upper Limb Prostheses produced with Additive Manufacturing

Catarina Hoosseni

Mestrado Integrado em Engenharia Biomédica e Biofísica
Engenharia Clínica e Instrumentação Médica

Dissertação orientada por:
Prof. Dr. Nuno Matela
Prof. Dr.ª Helena Canhão

2020

ACKNOWLEDGEMENTS

2020 has not been an easy year. We used to think that our major threats were things our eyes could see, such as wars, natural catastrophes or even economic crises. However, at the beginning of this year, we realised how small the world is and thus, we could experience some direct negative effects of globalization - a pandemic crisis. Due to something that our eyes could not see - a virus, everything was impacted. My dissertation, as well as my colleagues' dissertations were not an exception. Everyone had to try and implement new ways of working. My journey was odd, I may confess, but I have some acknowledgements to do.

I would first like to thank my supervisor Prof Nuno Matela, for his kindness and professionalism. I am very grateful for the time he spent guiding and explaining me the right way during this journey.

Secondly, I would like to thank Professor Helena Canhão and Salomé Azevedo from Patient Innovation. They helped me and guided me in the first steps of my dissertation, which I found very useful to the final output. I also need to mention the meaningful support Catarina Santos (from Patient Innovation) gave me. If Professor Pedro Oliveira (from Patient Innovation) would not crossed my way, it would have been impossible to know this incredible organization (Patient Innovation) with such a big purpose. So thank you, Professor Pedro.

Finally, I must express my very profound gratitude to my family, specially my mom and dad, and to my friends for providing me with unfailing support and continuous encouragement throughout my years of study and through the process of researching and writing this dissertation. This accomplishment would not have been possible without them. Thank you.

ABSTRACT

Many times, upper-limb prosthetic devices specially developed for children arise as a concern of parents whose children have congenital handicaps and want to start using a device. In this perspective, the aim of this work is to develop fully functional body powered, low-cost upper-limb prostheses, customizable for each child and evaluate the 3D printed technology for this purpose.

There is a clear gap in devices designed for children. They need to be affordable, since children are constantly growing and there is a risk of breaking them while playing. Cosmetic devices have no function and electric-powered devices are very costly, and not accessible to every family. Thus, 3D printing body-powered prosthetic devices seem to be a good option.

The e-NABLE community is a worldwide group of individuals who are using their 3D printers to create free 3D printed hands and arms for those in need of an upper limb assistive device. All designs are open source, which allows people who have access to a 3D printer to download the designs and print their own prostheses at a low cost.

This work was carried out in Patient Innovation, in the scope of the "Give a Hand" project. This project's mission is to adapt open-source designs and 3D printed prostheses customized for children (between 3 and 12 years old) who do not have a hand or arm and give it to them for free. In this work, two upper limb 3D printed prostheses were developed for two different cases studies (5 years old, right hand and 10 years old, left hand). These 3D printed upper limb prosthetic devices (created by e-NABLE) are affordable and relatively fast to produce. They can be seen as the first prosthesis of a child and their main purpose is to give power to the child to decide, in his/her adult life if he/she would like to have a device.

Key words: 3D printing, upper-limb, children, additive manufacturing, prostheses.

RESUMO

Infelizmente, existem crianças que apresentam uma deficiência do membro superior. Esta pode ser causada por alguma amputação, mas também pode ser fruto de questões congénitas, como é o caso da síndrome da brida amniótica. Perante esta condição, existem partes da membrana do saco amniótico que, ao funcionar como um cordão fibroso, podem comprometer a circulação sanguínea ou até mesmo levar a deformidades nos membros.

Apesar de não existir cura para esta condição, a inovação na área da saúde tem aqui um papel extremamente importante. Neste trabalho, os vários tipos de inovação são descritos: inovação aberta vs. inovação fechada, a inovação do utilizador e, por fim, a inovação por parte do doente. Neste contexto, é introduzido o Patient Innovation (PI), uma associação que compreende uma plataforma online onde doentes e cuidadores de todo o mundo se ligam para partilhar soluções que os próprios desenvolveram, ou que criaram com a ajuda de um colaborador para ultrapassar um desafio imposto por um problema de saúde. Para além disso, associada ao PI, surge o projeto Dar a Mão. A missão inerente deste projeto consiste na adaptação de desenhos "open source" e impressão em 3D de próteses customizadas a crianças (dos 3 aos 12 anos) que nasceram sem mão ou antebraço. O principal objetivo do projeto é produzir e doar próteses dos membros superiores a crianças, e desta forma dar resposta aos vários pedidos de famílias que necessitam de próteses impressas em 3D. A utilização desta solução terá um impacto direto na inclusão destas crianças na sociedade e permitirá aos pais motivar os seus filhos a serem mais independentes e a não deixar que uma condição física altere as suas metas. O segundo objetivo prende-se com a criação de uma rede nacional de voluntários que potencie o desenvolvimento e produção sustentável de próteses a baixo custo para crianças com limitações físicas. Por fim, o terceiro objetivo é contribuir para um movimento social através da formação dos familiares da criança com deficiência que os estimulará a melhorar e adaptar os modelos de prótese existentes às necessidades da criança. Desta forma, este trabalho teve como principal objetivo o desenvolvimento de próteses para o membro superior a baixo custo, recorrendo à manufatura aditiva.

Atualmente existem três tipos de próteses: as passivas/cosméticas, as próteses mioelétricas e as próteses alimentadas por energia gerada pelo próprio corpo. As próteses passivas/cosméticas têm um propósito meramente cosmético e de parecerem semelhantes ao outro membro. As próteses mioelétricas/braços biónicos que são controladas pelos sinais elétricos produzidos aquando da contração muscular. Este segundo tipo de equipamentos costuma ser caro e não adequado à idade pediátrica, uma vez que as crianças apresentam um crescimento bastante rápido e ao brincar podem partir ou danificar a prótese. Existe o terceiro tipo: as próteses alimentadas por energia gerada pelo próprio corpo. Normalmente, estas próteses possuem um mecanismo simples e são leves comparativamente às anteriores. De acordo com a literatura, existe um

número considerável deste tipo de próteses construídas através de impressão 3D. A *e-NABLE: Enabling the Future* é um projeto sem fins lucrativos que trabalha com ficheiros "open source", permitindo que as suas próteses sejam usadas em qualquer parte do mundo.

Durante esta dissertação, foi feita a recolha de dados dos vários sujeitos e foram desenvolvidas duas próteses, recorrendo à técnica de manufatura aditiva com uma impressora 3D de *fused deposition modeling* (FDM) e o filamento utilizado foi ácido polilático. O primeiro sujeito tinha 6 anos e, devido à síndrome da brida amniótica, não tinha parte do membro superior direito. Durante o desenvolvimento desta prótese, surgiram algumas questões relacionadas com a própria impressão. O segundo sujeito tinha 10 anos e também devido à mesma causa, não possuía parte do membro superior esquerdo. Ao longo do trabalho e de forma avaliar a função e espontaneidade de utilização da prótese por parte da criança, foi testado um modelo de medição dos resultados após alguns meses de uso. Contudo, este modelo revelou-se inconclusivo.

A pandemia por Covid-19 impactou alguns dos resultados desta dissertação, uma vez que não foi possível entregar a segunda prótese ao sujeito em tempo útil, e por conseguinte não foi possível estudar um novo modelo de medição dos resultados.

Os modelos de próteses de membros superiores criados pela e-NABLE são relativamente acessíveis e rápidos de adquirir, quando comparados com outros modelos. Concluíndo, a utilização destas próteses por parte de crianças, é uma forma de elas terem um primeiro contacto com um equipamento deste género, para, no futuro, poderem optar por utilizar uma prótese ou não.

Palavras-chave: Impressão 3D, membros superiores, crianças, manufatura aditiva, próteses.

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LIST OF ACRONYMS

3D	Three-Dimensional
LDDs	Limb Deficiency Disorders
EMG	Electromyography
AM	Additive Manufacturing
FDM	Fused Deposition Modeling
FFF	Fused Filament Fabrication
SLS	Selective Laser Sintering
SLA	Stereolithography
PLA	Polylactic Acid
ABS	Acrylonitrile Butadiene Styrene
PET	Polyethylene Terephthalate
CAD	Computer Aided Design
VC	Voluntary Closing
FDA	Food and Drug Administration
EMA	European Medicines Agency
PI	Patient Innovation
ICF	International Classification of Functioning, Disability and Health
QOL	Quality of Life
ACMC	Assessment of Capacity for Myoelectric Control
UNB	University of New Brunswick
AHA	Assisting Hand Assessment
PUFI	Prosthetic Upper Extremity Function Index

CHAPTER 1

INTRODUCTION

1.1 MOTIVATION

The human hand is an extraordinary natural feat of engineering in the human body because it gives us a powerful grip and also allows us to manipulate small objects with great precision, from an early age. This is what makes us different from most other living beings [1]. The loss of one hand can significantly affect the level of autonomy and the capability of performing daily living, working and social activities [2]. Furthermore, it strongly affects the subjects' self-esteem and this has severe consequences in children's behavior in particular.

The limb malformation disorders (LDDs) are defined as a broad group of congenital anomalies featuring significant hypoplasia or aplasia of one or more bones of the limbs and they can occur in isolation or associated with other anomalies [3]. According to the Center for Disease Control and Prevention (USA), each year about 4 out of every 10,000 babies will have upper limb reductions [4]. In order to help these individuals dealing with their condition, efforts have been done to create prostheses. However, sometimes buying a prosthesis is costly [5] and the device is heavy, resulting in non-usage by the child. Over the last 5 years, significant development has occurred in 3D-printing of upper limb prostheses [6].

In this perspective, people are developing prostheses, and large communities, such as e-NABLE, have been established. The e-NABLE Community is a group of individuals (engineers, 3D-printing enthusiasts, occupational therapists, university professors, designers, parents, families, artists, students, teachers and people who have developed 3D-printed prostheses) from all over the world who are using their 3D printers to create free 3D printed hands and arms and offer them to those in need of an upper limb assistive device [7].

1.2 UPPER-LIMB MALFORMATIONS

1.2.1 MAIN CAUSES OF UPPER-LIMB MALFORMATIONS

Children with limb malformations (loss of any part of the limb) have either *congenital limb malformation* (present at birth) or *acquired limb amputation*. According to Al-Worikat *et al.* [8], demographic studies suggest that there is a preponderance of the congenital limb malformations to acquired limb amputations, specially in developed nations [9].

Congenital malformation may be caused by factors such as genetic syndromes or amniotic bands. In the latter (also called Streeter dysplasia or constriction bands), the bands cause an intrinsic defect in the growth of the fetal limb. It means that there is partial or total absence of the limb. This rare disorder occurs in 1-10 000 births, with no sex correlation [10].

The developing embryo sits within two cavities, the amnion and the chorion (see Figure 1.1). As development occurs, the amnion presses against the extracoelomic space, and at approximately week 12 of gestation, could eventually obliterate it and bring the amnion up to and supported by the chorion. The amnion can become fragile and prone to spontaneous or traumatic rupture, if there is an incomplete elimination of the extracoelomic space [11]. After a rupture, a transient oligohydramnios occurs due to extravasation of amniotic fluid. The developing fetus has very little available room to move, until the chorion adjusts to the permeability. With this space reduction, the resulting floating amniotic bands can easily ensnare a developing body part and depending on the time frame, it can lead to different consequences, for example, in early gestation, the encircling bands may result in spontaneous abortions. If the development is nearly complete, it can cause fissures and deformities in the limb extremities.

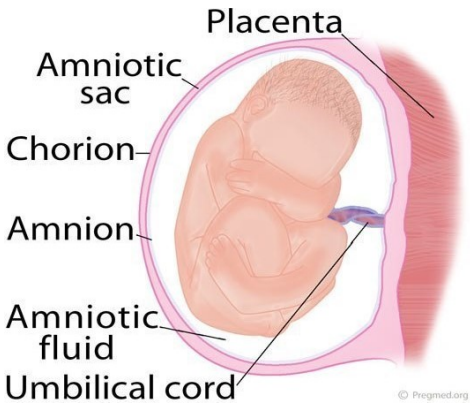


Figure 1.1: Representation of the amniotic sac [12].

Congenital malformations can be classified as transverse (where the distal part of the extremity is lost and the proximal part is relatively normal), longitudinal (where one side of the limb is affected), intercalary (where the proximal and distal limb are relatively unaffected with an intervening affected segment) and terminal (when the deformity extends to distal part of

limb) [8] [9]. Frantz and O'Rahilly [9] created a system to classify congenital limb malformations (see Appendix A). In Figure 1.2, the skeletal deformities of the upper-limb are represented:

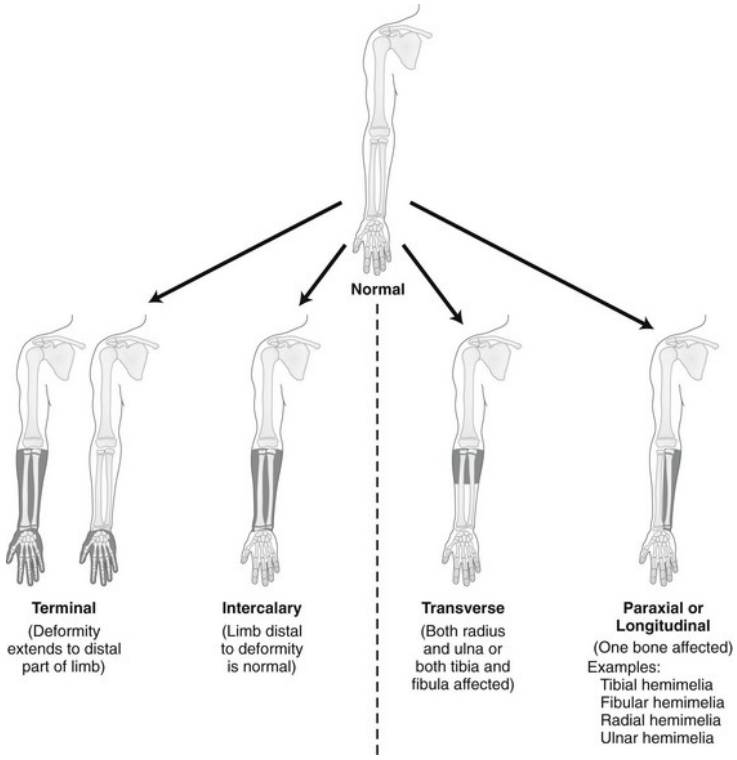


Figure 1.2: Skeletal deformities of the upper-limb. The shaded areas represent malformations [13].

Conversely, an amputation is an acquired condition that results [14] in the loss of a limb, usually from trauma (vehicle accidents, machine accidents and power tools, blast explosion and burn injuries), severe systemic infection (meningococcemia), or malignant tumour. Al-Worikat *et al.* [8] explained that, in their study, after tumours, trauma was the second highest cause of limb malformations. Traffic accidents were the predominant cause of trauma and the second type was machine and power tools accidents which caused amputation in children in their study and in the majority of other studies.

1.2.2 Psychosocial Aspects in Limb malformation Patients

The Parents

After a child being diagnosed with a congenital deformity or congenital amputation, the ones who will need more attention at first are the parents. This is mainly because of their emotions and expectations of treatment. They tend to feel guilty, shocked, helpless and often they do not understand the reason behind it. Afterwards, parents will have many questions about their child's future and, in this process, it is very important for them to meet children with similar

malformations and to see what their child might be like in the future [9].

THE CHILD

Regarding the perception of his/her handicap, studies suggest that children's understanding of their disability is general and incomplete at 6 years of age, but around the age of 8 or 9 years of age, they start to be aware of it [9]. Additionally, all children with disabilities are vulnerable to social isolation, negatively affecting the development of self-esteem, body image and the child's identity. This is due to their interaction with parents, teachers, friends, classmates and others. Furthermore, children have been proven to show signs of anxiety when face-to-face with a person with a limb malformation. This problem can be solved, for instance, by organizing discussions with classmates in school about it.

According to Bowen *et al.* [9], there is evidence demonstrating that the age of the patient, the gender, the degree of limb loss, or socioeconomic status are not predictors of low self-esteem or depressive symptoms. However, social factors such as stress, parental discord, and social support from classmates, parents, and teachers, along with the child's own perceptions of competency and adequacy, gained through peer acceptance, scholastic achievement, and athletic accomplishments, play the largest role in the development of self-esteem [9].

1.2.3 CLINICAL PROCEDURES AND EXISTING TREATMENTS

Indications for medical interventions to treat amniotic band syndrome depend on the medical stability of the child as well as on the neurovascular status of the limb [15]. Mild bands that only cosmetically affect the skin do not require any intervention. According to Twee [15], as growth occurs, progressive constriction and edema may need band excision and a plastic surgery intervention. However, in general, excision is not indicated for superficial bands, because of the potential neurovascular compromise and complications due to wound infections.

There is no treatment for amniotic band syndrome, since this is an intrauterine phenomenon probably caused by the rupture of amniotic membranes and constriction of the developing tissue [15]. Cocaine and mifepristone have been proven to lead to spontaneous rupture of membranes [15].

Surgical treatment is indicated for patients with conditions that compromise the limb function. In the case of thumb amputation, clubfeet and cleft lip, specialists recommend these procedures at a later time in life [15] [16]. In bands identified by 3D ultrasonography as causing neurovascular compromise, a procedure called in-utero fetoscopic surgery can be performed [15]. It has been proposed as an alternative to open fetal surgery - fetoscopic surgery, since

it has been shown to have decreased maternal morbidity as compared to the first [17]. In this procedure, an instrument called laparoscope is inserted into the uterus, so that it is possible to see the fetus and the placenta. Regarding the amniotic band syndrome, fetoscopic releases have been reported as effective on the outcomes for the constrictions affecting the fetus and the relative safety of the procedure to the mothers [18] [19] [20] [21] [22].

According to Twee [15], complications from amniotic band syndrome include severe lymphatic or venous congestion at the time of birth due to tight bands, leading to necrosis and gangrene, if not urgently treated with excision and release.

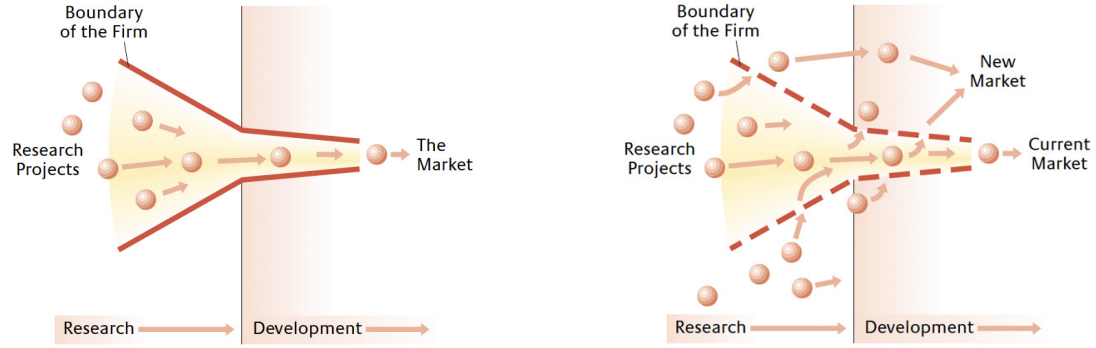
1.3 Innovation and its Importance in Healthcare

The word "innovation" has a number of meanings [23]. Innovation can be described by the following formula: $Innovation = Invention \times Commercialization$. It means that it has to be something new (an idea or technology, for example) and that it is necessary an organization to commercialize it. It is mandatory to have both concepts (invention and commercialization) involved in the innovation term. With these two concepts, innovation is defined as a process or a series of steps which begin with imagination and results in the creation of something of value to the world.

In a context of increasing globalization, international competition and ageing population, many organizations feel the urge to stimulate innovation, in order to secure long-term wealth creation [24]. Specifically in the healthcare sector, by innovating, it is possible to improve the ability to meet public and personal healthcare needs and demands by optimising the performance of the health system. According to Kimble [25], the World Health Organization (WHO) explains that 'health innovation' improves the efficiency, effectiveness, quality, sustainability, safety, and/or affordability of healthcare. This definition includes 'new or improved' health policies, practices, systems, products and technologies, services, and delivery methods that result in improved healthcare.

1.3.1 Open Innovation

In *closed innovation*, a company generates, develops and commercializes its own ideas. This philosophy of self-reliance was adopted by the R&D (research and development) operations of many leading industrial corporations for most of the 20th century (see Figure 1.3a).



(a) The closed innovation model.

(b) The open innovation model.

Figure 1.3: Types of innovation models. [26]

Nowadays, many companies agree that internal R&D becomes expensive, uncertain and slow, while facing constant innovation challenge. In this perspective, many of them are considering outside sources of basic technology, shortened product development time, or applied technology to avoid the costs and delay of research and development [27]. Chesbrough, the writer of the book "Open Innovation: The New Imperative for Creating and Profiting from Technology" and creator of the term *open innovation* (see Figure 1.3b), defined this as "a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as firms look to advance their technology" [26].

Regarding its advantages, open innovation enables to screen projects that may have commercial value in the future, allowing intellectual property, ideas and people to flow freely both into and out of an organization [28]. Besides that, A. King and K. Lakhani (2013) cited that if there are ideas for solutions coming from anywhere, then it is more likely to have a better quality of the best idea. They also stated that outsiders have distinctive expertise and perspectives, which enable them to pick winning ideas [24].

When choosing to adopt an open-innovation strategy, managers must choose whether to open the idea generation process, the idea-selection process or both, as described in Figure 1.4:

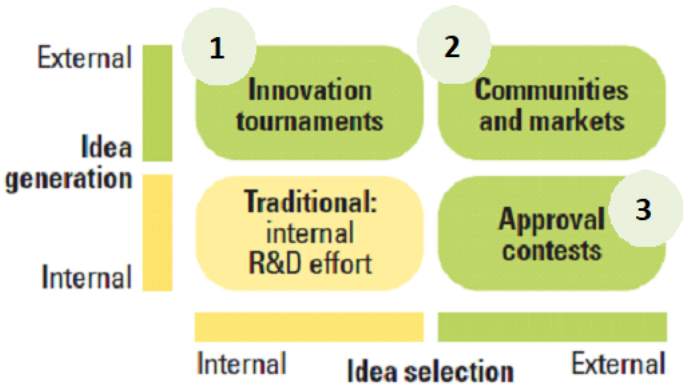


Figure 1.4: Selecting the right innovation approach. [24] 1. Opening the Idea-Creation Process; 2. Opening both the Idea-Creation and Selection Process; 3. Opening the Idea Selection Process.

In order to facilitate and increase the generation of ideas (Figure 1.4, 1), many organizations are turning to innovation contests and the value is based on the number of participants and quality of the ideas. An enormous challenge relies on who is the owner of the future ideas. Managers are less familiar with the second option: opening the idea-selection process (see Figure 1.4, 3). As an advantage, it allows companies to shift costs and risks to outsiders. However, while outsiders may have unique insights into the value of an idea, their concept of value is not always aligned with the company's strategy, brand or profit goals. The third approach (Figure 1.4, 2) is typical from organizations focused on products where needs change quickly. In this scenario, they must confront the problems noted earlier and they also must address what is potentially a more fundamental problem.

Despite the advantages of open innovation, a company should be prepared for the challenges (cultural, political and organizational) of applying it. External issues with partners, clients, suppliers and costumers need to be negotiated [28]. It takes time to change employees' perception and managers should study all the advantages for their specific situation.

1.3.2 User Innovation

Eric von Hippel is a Professor at the MIT Sloan School of Management and he is best known for his work in developing the concept of *user innovation*. According to him, there is a user innovation when the person who develops it expects to benefit by using the innovation. Users can sometimes explain with accuracy their current and future needs to a manufacturer. There is the concept of *producer/manufacturer innovation* and it occurs when the developer expects to benefit by selling the innovation. Surprisingly often, ideas for new or improved products come first from users who develop improvised versions to help them to cope with their own needs. Manufacturers then may discover, polish and capitalize on user innovations — particularly if

those innovations begin to catch on with a group of users [29].

Studies developed by von Hippel showed that in eight out of ten cases, six years before a firm starts commercializing innovations, it was the users that developed it. The *lead users* are particularly important - sophisticated users who are the most likely to innovate to satisfy their own needs [29].

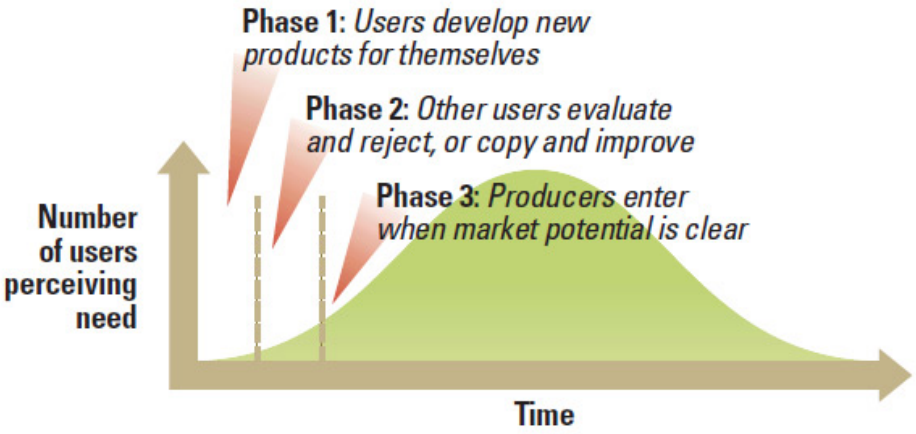


Figure 1.5: A new innovation paradigm: user innovation [29].

In Figure 1.5, von Hippel [29] describes the user innovation approach: In **Phase 1** - the earliest stage of a market - users often innovate to create the products they want and need. In **Phase 2**, there was information diffusion and other users either reject or validate the initial innovation. If others adopt the initial innovation, it means that it was validated. Finally, in **Phase 3**, after the market opportunity has become clear, the market grows enough to be interesting to producing companies, which refine and commercialize the innovation for sale to a growing market of users.

Single user innovation and open collaborative innovation are the invisible but essential feedstocks for the industrial innovation engine and it is the industry's and society's best interests to protect the "innovations commonspace".

Diffusion of User Innovations

After creating a successfully novel solution, user innovators are faced with a challenge [30]:

- They can become entrepreneurs;
- They may sell or license their idea;
- They can freely reveal their idea to a community;
- If they do nothing to diffuse their innovation, perhaps a valuable contribution to the world is lost.

Diffusion of user innovations may generally be separated between *market diffusion* and *peer-to-peer diffusion*. In the first case, users either become user entrepreneurs, sell or license their innovation for commercialization by an existing company. The second case comprises negligible cost in the transfer of innovation-related information to potential adopters [31] and is usually due to individuals or an established community. Diffusion to non-potential adopters is included because by spreading the information of a certain innovation to them, it may be a means to reach potential adopters. In addition, the two forms of diffusion may be performed in sequence, meaning that a user could share his/her innovation to his/her community and later become a user entrepreneur [31].

PATIENT INNOVATION

According to Oliveira *et al.* [32], the high patient need together with the low commercial activity in rare disease marketplaces create both a need and an incentive for patients and their caregivers to innovate themselves to help to contribute to many quality of life issues. *Patient Innovation* is defined by Kanstrup *et al.* [33] as patients' development of ideas, practice or objects that are perceived as new by themselves and/or by others within the social system of adaptation. In this perspective, this csincept is not analysed in comparison with high-technological innovation or market shares. Instead, it is defined and analysed in relation to the existing practice of patients and their social system of adaptation.

- **The Platform**
  The larger project where this dissertation is being carried out is also called Patient Innovation (PI). This is an online platform where patients and caregivers around the world connect to share and create solutions they developed to cope with a health-related problem.

- **The "Give a Hand" Project**
  Within the scope of the work the behind Patient Innovation platform, there is a growing project named "Give a Hand". This project illustrates the concept of Patient Innovation because its mission is to adapt open-source designs and 3D printed prostheses customized for children (between 3 and 12 years old) who do not have a hand or arm and give a prosthesis to them for free. The project has three main goals. The first is to produce and donate upper limb prostheses to children and, in this way, answering to this family's demand. The second is to create a national network of volunteers who will help in the sustainable development of low-cost prostheses for children with disabilities. Finally, it is also necessary to create a social movement through the training of families and thus, improving the models to the children's needs.

1.4 AIM OF THE WORK & PROJECT OVERVIEW

The main goal of this dissertation is to develop fully functional body powered, low-cost upper limb prostheses, to customize them for each child and evaluate the 3D printed technology for this purpose.

In this first chapter, the motivation is described together with two main topics, which are in the origin of the project: upper-limb malformations and innovation. In the second chapter, there is the literature review, explaining details regarding upper-limb prostheses: types, components, 3D printing technology and 3D printed prostheses). The third chapter shows the main results of this dissertation, with some case studies. Finally, the overall conclusion is presented, as well as some considerations to take into account in the future, to continue this project.

CHAPTER 2

LITERATURE REVIEW

In this chapter, the types of prostheses are described, as well as some relevant components (sockets, grips and hand movements). Finally, 3D printing technology and 3D printed prostheses are presented.

2.1 TYPES OF PROSTHESES

When a prosthesis is suitable for the patient, it can both help in his/her rehabilitation and improve his/her life. The ultimate goal of a prosthesis is to restore as many functions as possible from the missing body part, providing a simple and natural feeling for the user [34]. There are three main categories of prostheses available for the patient: passive, body powered and myoelectric.

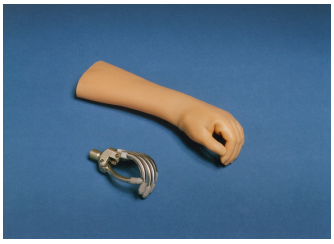
2.1.1 PASSIVE PROSTHESES

Passive prostheses (see Figure 2.1) are also known as cosmetic prostheses and they are being developed primarily for aesthetic reasons, while providing an extension of the limb [35]. Cosmetic hands and arms are available with several designs and materials and are often developed to resemble a normal human hand, without functional features. For example, when the patient does not have one of the arms, the prosthesis is created based on the other existing arm. Studies carried out by McGimpsey *et al.*, 2008 demonstrated that it is possible to purchase highly realistic cosmetic arms for a cost surrounding US$3,000 to US$5,000, allowing the user to be in public without standing out [5].

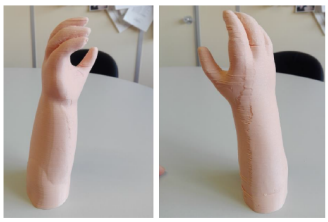
These passive devices can also perform a moderate function. As shown in Figure 2.1b, the prosthesis has a manually adaptive opening grip claw which allows the patient to choose different opening angles and even pick up objects with manual assistance. This claw is covered

with a cosmetic glove, ensuring a realistic appearance. It is also possible to develop 3D printed passive prostheses using low cost and flexible filaments [36], such as *Filaflex* ®.

(a) Hand prosthesis for adults (Livingskin ™) [37].



(b) The WILMER Hand Prosthesis for Toddlers [38].



(c) 3D Printed Prosthesis with *Filaflex*®[36].

Figure 2.1: Examples of passive upper limb prostheses.

2.1.2 ELECTRIC-POWERED PROSTHESES

Functional prosthetic arms and hands can be broadly categorized into two groups: externally-power and body-powered prostheses [39]. Myoelectric prostheses, also known as bionic arms/ hands are included in the first group, meaning that they are controlled by electrical signals produced in a muscle when contracted. Potential changes in activated muscles in the residual limb are registered by electromyography (EMG) sensors. These sensors can be located in the socket, on the skin (above the targeted muscle) or implanted on the muscle itself [35]. Regarding the first option, it is easy to understand that it has some powered related disadvantages: it is limited to superficial muscles and susceptible to myoelectric crosstalk (interference), motion artifacts, and thus considerably degrading the controllability of the prosthesis. In this perspective, when sensors are implanted the electric signals are stronger, since they do not travel through tissue before registration [40]. Afterwards, the signals are used as commands for the terminal device, meaning that an intentional contraction in a muscle will move the artificial hand in a specific way.

Nowadays technology provides upper limb myoeletric prostheses ranging those with only an open or close function to very complex and sophisticated devices with many hand movements. Therefore, increased precision is associated with more components as well as more powerful batteries [35]. More components (battery, motor, etc.) sometimes mean that there is an increased weight and cost, and these are the major drawbacks of these electric-powered devices [39]. Regarding the cost, myoelectric prostheses are the most expensive with a cost between US$20,000 and US$30,000 [5]. However, as technology advances, the weight and price of each component will eventually become lighter and cheaper, respectively.

As an example, the BeBionic™hand is, displayed in Figure 2.2. The BeBionic™is defined as one of "the most advanced myoeletric prosthesis in the market". Since it is a high-tech

and high-priced device, it allows for individual finger control with high precision and can be manually adapted for different kinds of grips.

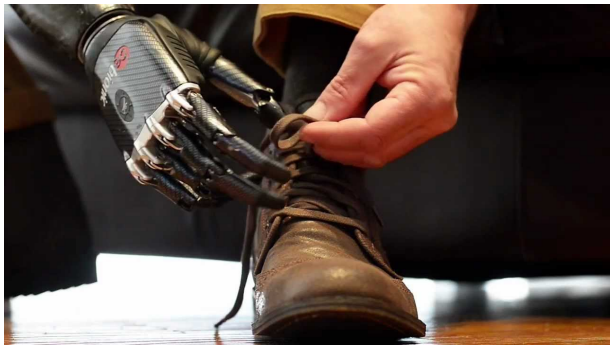


Figure 2.2: The BeBionic^{TM}hand [41].

2.1.3 BODY-POWERED PROSTHESES

Body-powered prostheses use the body of the patient to mechanically control the movements [35]. Hands, forearms and elbows may be controlled by a system of harnesses attached to portions of the the patient's body that have maintained their natural movements. Unlike the previous type of prostheses, body-powered prostheses can be used in environments involving dust and water. Additionally, the advantages of body-powered prostheses include having simple operational mechanisms with intrinsic skeletal movement, silent action, light weight and moderate to low costs [42]. It is very common to attach the device to a shoulder harness, as seen in Figure 2.3.

Figure 2.3: Arm prosthesis attached to the body with a harness [43].

There is a considerable number of body-powered prostheses produced using 3D printing technology. e-NABLE: *Enabling the Future* is a very well-known nonprofit project working as an open-source basis and allowing their prosthetic devices to be printed and used all over the world [7]. More details about e-NABLE are further provided in Section 2.5.1.

2.2 SOCKETS

The socket is the part of the prosthesis enabling the contact between the residual limb and the prosthesis, thus it plays an important role for the success of the entire prosthesis. It strongly impacts the comfort, function and individual opinion of the prosthetic device. By creating an inadequate socket, instead of bringing well-being to the patient, it causes pain, bruises and blisters, leading to little or no adhesion. Since upper limb malformations are different, it is necessary to adjust the socket so that it can carefully fit the user limb. The goal is to develop a socket that distributes the load evenly to limit the pressure of the device [35]. It is important to update and replace the socket regularly due to the fact that the residual limb will change over time, specially in children.

Several strategies have been used to create sockets. The traditional way is using plaster. After forming a negative cast, a positive is created. Afterwards, a test socket is made with transparent thermoplastic and vacuum. The final step comprises creating the final socket in a suitable material in the same way as the test socket [35]. However, this process is seen as being both time consuming and a manual labour-intensive process. By using today's 3D technology (scanners, printers and various software) it is easier to recreate complex geometries. E. Stromshed (2016) [44] developed "the Perfect Fit-process". It uses a low-cost 3D scanner mounted on an iPad to collect patient's data in the form of a digitalization of the residual limb. A 3D modelling software modifies these data, allowing the creation of perfectly fitted sockets both for passive as well as myoelectric prostheses (see Section 2.1).

2.3 GRIPS AND HAND MOVEMENTS

When referring to hand movements in prostheses, it is common to talk about different grip patterns, which is a combination of positions and movements of fingers. Figure 2.4 shows six different grip classifications used in the Southampton Hand Assessment Procedure (SHAP) [45] a clinical test design to measure a hand's functional range.

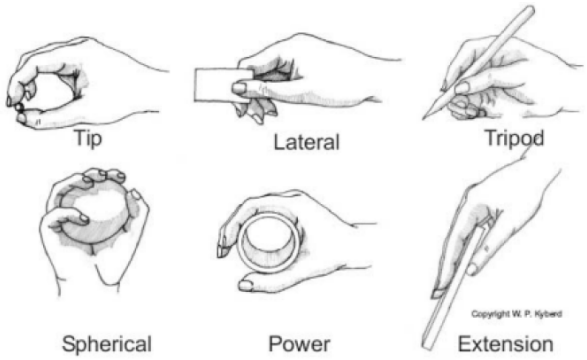


Figure 2.4: Different grip patterns included in the Southampton Hand Assessment Procedure [45].

2.4 3D Printing Technology

Additive Manufacturing (AM) [46] is a term which describes the technologies that builds 3D objects by adding layer-upon-layer of material. Common to AM technologies is the use of a computer, 3D modeling software (also called Computer Aided Design, CAD). AM application is limitless. It started as a form of Rapid Prototyping focused on pre-production visualization models and more recently, it is being used for medical implants, prostheses and dental restorations, in the context of health interventions.

There are many different types of 3D printers, which differ in the method of layer application and bonding, but the main steps of the procedure are the same. Firstly, the idea is to slice the virtual three-dimensional model into very slim cross-sections and create an STL file (short for stereolithography). This 3D printer compatible file is, afterwards sent to the printer for extrusion. There is more or less post-processing of the model according to the printing type [35]. Nowadays, there are several different types of 3D printing technologies used by 3D printers [47]. Fused Deposition Modeling (FDM) is the one used during this dissertation, whose 3D printer is Colido X3045 and Prusa Slicer. Additionally, in this dissertation Selective Laser Sintering (SLS) is discussed because it is another widely used technique.

2.4.1 Fused Deposition Modeling (FDM)

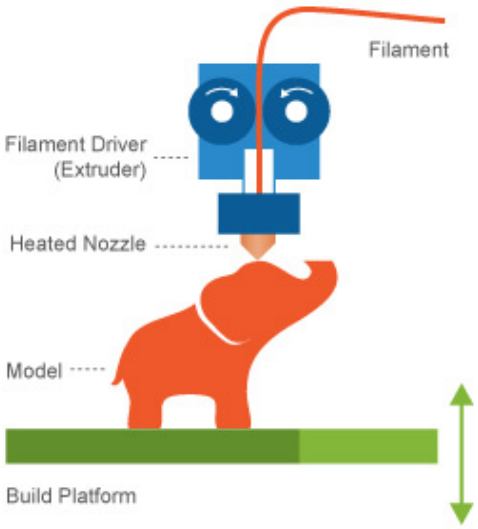


Figure 2.5: The mechanism behind FDM technique. A thermoplastic material is extruded through a nozzle, layer by layer, creating the model over the build platform [48].

FDM is also called Fused Filament Fabrication (FFF) and, in general, it is the most used technique. This is because of the low price of the printer and the easy manipulation, which makes it possible for home use [49]. In this 3D printing technique (see Figure 2.5) the material used in a FDM printer is thermoplastic (PLA, ABS - see Section 2.5.2). The filament is heated up and extruded through a nozzle onto a build platform. This is continuously moving downwards resulting in the solid object (model) emerging layer by layer [35]. Depending on the object's complexity and geometry of the object, support structures may be added [47] and the roughness of the 3D-printed structures is an important issue, since it affects not only the appearance, but also the mechanical resistance of the printed objects [49].

2.4.2 Selective Laser Sintering (SLS)

Selective Laser Sintering (SLS) uses a 3D printing process called Power Bed Fusion [47] with the help of both a powder material and a laser to build a 3D object. Firstly, a thin layer of the powder is spread out on the build platform and secondly, the energy from a laser beam is used to melt it into a solid shape, a process called sintering. As previous described in the FDM scenario, the platform is continuously moving downwards so that another layer of powder can be added. As soon as the new layer is hit by the laser beam, it is melted and fuses to the structure below. Unlike the FDM technique, it is not necessary to build other material to hold up the structure because the powder itself works as a support material [35].

2.5 3D Printed Prostheses

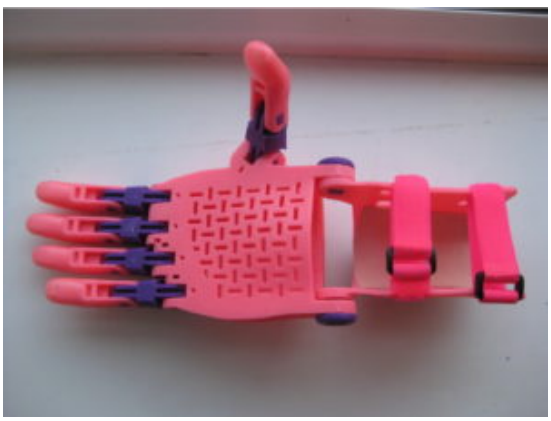
With the developments done in 3D printing techniques, more advances in 3D printed prosthetic devices have emerged. With the purpose of providing cheap and easily manufactured equipment for amputees in developing countries [35], CAD designers and enthusiasts have come together to create foundations and organizations which provide open source prosthetic devices.

2.5.1 e-NABLE Community

In this perspective, people are developing prostheses individually, and large communities, such as e-NABLE, have been established. The e-NABLE Community is a group of individuals (tinkerers, engineers, 3D-printing enthusiasts, occupational therapists, university professors, designers, parents, families, artists, students, teachers and people who have developed 3D-printed prostheses) from all over the world who are using their 3D printers to create free 3D printed hands and arms for those in need of an upper limb assistive device [7]. All designs are open source, which allows people who have access to a 3D printer to download the designs and print their own prostheses at a low cost.

The most common designs available in this platform are for transcarpal amputees (see Figure B.1, in Appendix B) with a functional wrist, with at least 30 degrees range of motion, as shown in Figure 2.6b. Further to this, there are also some designs available for transradial amputees with only a functional elbow - see Figure 2.6a.

(a) The UnLimbited Arm 2.1 is an elbow-driven device [50].



(b) The Unlimbited Phoenix Hand is a wrist-driven device [7].

Figure 2.6: e-NABLE designs available for upper limbs. Many of the open source prostheses are intended for children and therefore have a playful design.

By observing the body powered 3D printable arms and hands available on the web, they have some design key points in common. Instead of having a socket, they have a printed half-

cylindrical gauntlet around the residual limb, attached and kept in place with Velcro bands. Most of the open source designs are voluntary closing (VC). In addiction, in contrast to the majority of the body powered prosthetic devices used clinically, there are no shoulder harnesses being used [35]. Instead, the prostheses can be controlled on the one hand through the wrist, because its flexion pulls on strings and closes the fingers (Figure 2.6b). On the other hand, the strings can be controlled by the elbow's flexion, closing the fingers (Figure 2.6b). Regarding the fingers, they either have two or three hinge joints each with one possible rotational direction. This means that the kid cannot close only one finger, he/she needs to close all or keep the hand opened. There are elastic strings running through holes in the fingers in order to keep the hand in its default position [35].

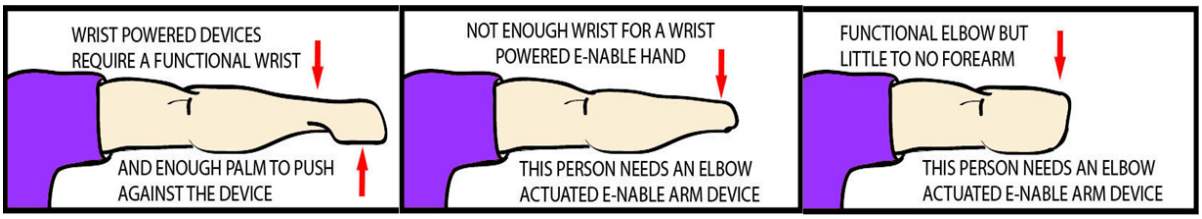


Figure 2.7: Diagrams helping in the decision of the most suitable prosthetic design [7].

2.5.2 Types of Filaments

Colido X3045, the 3D printer model available to print the prosthetic hands and arms, can either operate with PLA or ABS. The advantages and disadvantages of each one are here described.

Acrylonitrile Butadiene (ABS)

This type of material is used in FDM printers and is popular because it is lightweight and has good impact strength. It is also abrasion resistant and affordable. Moreover, it is relatively easy to glue and paint plastic products printed with ABS material, offering possibilities of customization. Vaporized acetone can be used to melt uniformly the surface of 3D-printed prostheses made of ABS [49]. However, it has a low melting point, which makes ABS not suitable for high heat situations [51]. Besides this, there have been recent csincerns about the toxicity of the printed ABS material when it is brought to its melting point, which, in fact has been proven due to the fumes it emits while exiting the extrusion head. Another downside is that this petroleum-based and non-biodegradable plastic can cause some skin irritation.

Polylactic Acid (PLA)

PLA is the most studied aliphatic polyester for biomedical applications, due to its clarity, biocompatibility, high mechanical strength and modulus, and facile processability through extrusion, injection molding or casting. According to Chiulan *et al.* [49], besides this, its lower coefficient of thermal expansion and non-adherent properties to the printed surface makes PLA

a suitable material for 3D printing. Another reason is the fact that it is already approved by FDA and EMA, making it suitable for fast transfer from production to clinical trials and fabrication of medical devices. The prosthetic devices are currently printed using this thermoplastic with a fusion temperature of 205 ºC.

2.5.3 THE USERS NEEDS

Before starting the csinception of the upper limb 3D printed prostheses and based on previous works [52] as well, as one the parents' csincerns, it is important to list what is the user (child) needing and what are the parents expecting from it:

1. **Affordability**: The price is specially important when talking about devices for kids. Firstly, because they are constantly growing so a device that fits today, no longer fits in seven months. Secondly, because kids are constantly playing and they can damage or break the prosthetic hand. In this way, these prostheses are being developed with less than 20 euro.

2. **Easy to learn and use**: The device should be operated in a simple way, so that the kid does not spend much time learning how to work with it.

3. **Comfort**: This characteristic is extremely important when talking about a device that stays with the kid all day. If it is not comfortable, the kit will not use it.

2.5.4 MODELING A PROSTHESIS

There are several CAD Softwares available. Some of them are open source, such as FreeCAD®[53]. There are other options like Fusion 360®[54] and SolidWorks®[55]. As some advantages, on the one hand, the first has a free license for students and was created by Autodesk. On the other hand, SolidWorks®is a software available some Univerity's computers.

E-NABLE prostheses, as seen before, have pre-made models. On the one hand, they are easier to implement, but on the other hand, sometimes it does not fit. For instance, if the residual limb still has a finger, the model needs to be adapted.

2.5.5 EXISTING UPPER-LIMB PROSTHETIC OUTCOME MEASURES

The importance of outcome measures relies on the conclusions drawn from quality measurements since it influences, in this case, our service. According to H. Y. N. Lindner *et al.* [56], the quality of an outcome measure lies in its ability to produce consistent results (reliability) that reflect the csinceptual basis that we intend to measure (validity). Before any conclusion on the psychometric evidence can be drawn about the outcome measure csincerning a particular diagnostic group, it is important to examine the psychometric properties of reliability and validity in

different samples because these two csincepts are sample dependent. Besides this, by detecting changes in the responsiveness of an outcome measure, it is possible to measure changes in the child's status regarding the use of the prosthesis. These scores obtained should be able to help clinicians to make clinical decisions [56].

In this scenario, and in order to evaluate the outcomes of the prosthetic device after some months, children are usually too young to fill in the form. This means that their caregivers need to do it. In this perspective, and having in mind that the majority of them lack time and expertise in measuring the outcomes, the metrics should not be abstract and the questionnaire should be appealing as well. In the researcher/clinician's point of view, data should have scientific value, meaning that many questions with an open answer constitute a problem when analyzing that.

A way of comparing outcome measures that use the same terminologies, is to link the content of the measures to the International Classification of Functioning, Disability and Health (ICF) [57]. ICF classifies human functioning into four components:

1. Body Functions and Structures;
2. Activities and Participation;
3. Environmental Factors;
4. Personal Factors.

Figure 2.8 displays the relations between the four components. The first three are well subclassified into domains and categories. This linking process was cited by some clinicians as a facilitator of the selection of an appropriate outcome measure and it enables to identify the aspects of health that are measuring or lacking in those measures [58].

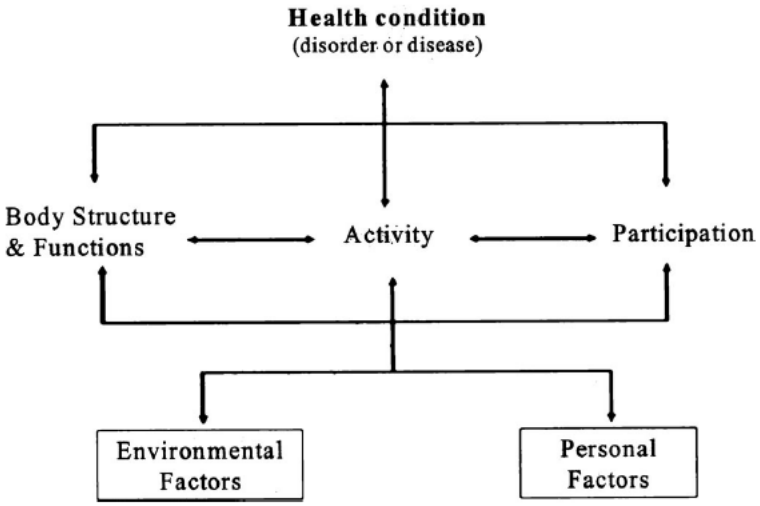


Figure 2.8: The International Classification of Function health framework displays the relationships among body structure and functions, activities and participation [57]. Source: [58].

In the last years, several assessments and questionnaires have been designed and validated on subjects with upper limb prostheses [58]. According to F. Virginia Wright [59], there is a separation between adult and pediatric upper limb prostheses users.

Although the use of standardized outcome measures for adults with upper limb (UL) amputations is uncommon in the published literature [59], future methods to assess impairment, activity level, participation, and quality of life (QOL) should address all aspects of measurement development and validation. Some examples of existing measures with the greatest psychometric strength are: The Jebsen-Taylor Test of Hand Function (JTHF), Box and Block Test (BBT), Assessment of Capacity of Myoelectric Control (ACMC), Upper Extremity Function Scale (UEFS), and Trinity Amputation and Prosthesis Experience Scales (TAPES).

Regarding pediatric upper limb prostheses users, the situation is quite different: greater advances in development of clinical measures and validation have been made for this purpose. The most promising measures are the Assessment of Capacity for Myoelectric Control (ACMC), University of New Brunswick (UNB) Test, Assisting Hand Assessment (AHA) and Prosthetic Upper Extremity Function Index (PUFI) [59].

ACMC is an observational assessment that has demonstrated being psychometrical promising. However, it is limited to users of myoelectric prostheses [59], which does not make it useful for this study. The UNB test [60], an observational measure, takes about half an hour to be completed. It contains ten functional items specific to each of four separate age groups (2-4y, 5-7y, 8-12y and 13-21y) and there are three subtests available online. This means that tasks change according to the age group. UBET was the weakest measure in the quality evaluation by two different studies [59] in terms of validity. The UBET was developed to evaluate function in bimanual activities for both the prosthesis wearer and non-wearer [61]. This test takes approximately twenty minutes and it has nine tasks for each of four age-specific categories defined by development stages of hand function (2-4y, 5-7y, 8-10y and 11-21y). UBET uses two scales to rate performance from 0 to 4: completion of task and method of use [61]. The AHA showed promising test-retest reliability and the ability to measure change. This test has focused on children with neurologically-based hemiplegia and there is no further information on AHA's measurement properties in prostheses [59]. Another drawback of this approach is that it requires a specific test kit and it is not freely available online [62]. PUFI is a amputee-specific measure and it has undergone further validation work following the developers' initial studies [59]. This test focuses on the ability to perform bimanual tasks with and without the prosthesis (ease of performance) and usefulness of prosthesis, rated on four multiple-level response scales [58]. [**Departments**].

After looking to all the methods available, it is easy to understand that it is likely desirable to use more than one measure to obtain a comprehensive picture of different aspects of hand function and prosthetic use [58]. Concluding, since these questionnaires are going to be filled in by the caregivers, a digital approach seems to enhance the engagement.

CHAPTER 3

DEVELOPMENT PROCESS

3.1 COLLECTING DATA

In order to understand the The "Give a Hand" Project, first of all, it is necessary to realise how the children are tracked. PI has a set of contacts, namely physicians (pediatric rheumatologists, pediatric orthopedists and physiatry) belonging to several hospitals located around Lisbon. Besides that, PI has a big presence in the social media. Thus, parents whose children have some disabilities can easily reach the association. Their first contact is usually a phone call in which they provide some details:

1. Status
2. Observation
3. Call to action
4. ID
5. Name
6. Date of birth
7. Age
8. Residency
9. Region (NUTII)
10. Means of identification
11. Found by whom
12. Agreed to participate in the program?
13. Responsible

14. Responsible contact
15. Diagnosis
16. Hand
17. Has the child use a prosthesis before?
18. Functional wrist
19. Functional elbow
20. Residency in Portugal
21. Eligibility to participate in the project?
22. Measures
23. Proposed color for the prosthesis
24. Model
25. Material
26. Scale
27. Delivered

In the first row ("Status"), the subject could have process completed, work in progress (on PI side) or not started (PI call), depending on the situation. In the observations, there is the data regarding when the first call was made and if the mother/father of the child failed to respond or provide further information. In the third row, the subject could have "Awaiting the prosthesis development", "Awaiting scheduling for evaluation"or "Awaiting scheduling for re-evaluation". As soon as the child is identified, PI assigns him/her an ID. The following five rows are personal data, namely, the name, the date of birth, the age, the residency and the region of the child. Furthermore, as previously mentioned, PI has a set of contacts and they are here described in the eleventhsrow. In order to respect the General Data Protection Regulation (GDPR), PI needs a consent, in which the responsible person agrees that the child participates in the program, while providing his/her contacts (phone number and email). The row called "Diagnosis" provides data on the cause of the upper limb deficiency and the majority of the study cases have the amniotic band syndrome. The row "Hand" specifies which hand has deficiencies (right or left). During the phone call, it is also asked if the child has used a prosthesis before. In order to create a suitable device, it is necessary to know whether he/she has a functional elbow or functional wrist. Row twenty is evaluated as being "True" or "False" if Portugal is the residency or not, respectively. From all this data, subjects are grouped in "Eligible" and "Non-eligible" to

participate in the "Give a Hand" project.

Regarding the measures (from A to H), these were done in specific body parts, following the Protocol (see Appendix C). During the evaluation of the children's arms, they were asked about the color of the device (and there were several options). The models here used are from e-NABLE. Finally, for the final model, there are some details to fill in, such as the material used (it was always PLA), the scale used and the date in which the prosthesis was delivered.

After the phone call, the child and their family were invited to do an evaluation of the upper limbs in PI's office. There, the measurements were taken as well as the photos. This process was carried out for seven children. After staring to work on one of the study cases, it was understood that besides having photos, it would be very useful having a video of the movement of the upper limb. This update facilitated the process of choosing the most suitable model. Thus, this was done for the following four study cases. Table 3.1 represents some relevant data on subjects involved in the data collection:

Table 3.1: Summary of the data collection of the eleven subjects.

Subject ID	Year of Birth	Gender	Hand	Diagnosis
#002	2014	Male	Right	Amniotic band syndrome
#012	2009	Male	Left	Amniotic band syndrome
#014	2011	Male	Right	Amniotic band syndrome
#015	2011	Male	Right	(missing data)
#016	2014	Male	Right	Amniotic band syndrome
#017	Adult	Male	Right	Work accident
#018	2008	Male	Left	Amniotic band syndrome
#020	2016	Female	Right	Poland syndrome
#021	2016	Male	Left	-
#023	2016	Male	Right	(missing data)
#024	2016	Female	Left	Amniotic band syndrome

3.2 Case Studies

3.2.1 Case Study 1

Patient Information

The first case study was from subject #002. By the time of the data collection (October, 2019), he was five years old and it has been told us that he did not have his right hand due to amniotic band syndrome (see Section 1.2.1). Figure 3.1 and Figure 3.2 display respectively the extension and flexion of the right arm:

Figure 3.1: Extension of the right arm (with deficiency) - Subject #002.

Figure 3.2: Flexion of the right arm (with deficiency) - Subject #002.

Development and Manufacturing Methods

Before starting to develop the model, it was fundamental to decide which design from the e-NABLE Community to choose (see Figure 2.7). Subject #002 has a wrist but it was not enough for a wrist powered e-NABLE hand. In this perspective, the person needs an elbow actuated e-NABLE arm device - UnLimited Arm 2.1 (see Figure 2.6a).

The first step was to go to the e-NABLE web page with this model [63]. This design uses the Thingiverse Customizer, a tool that makes easier the process to get the parts for printing in the desired scale. Firstly, it is asked to choose left or right hand and afterwards set the slider in the Customizer to the desired scale percentage. Finally, a ZIP file containing all of the parts (in the correct scale) is downloaded.

The printer used was CoLido X3045 and the filament was PLA (white color). Once this was the first prosthesis printed, we started by printing the smaller parts, meaning the fingers and

pins. The bigger parts, such as the forearm and the palm, were left to the end. After printing all the parts, it was necessary to module the forearm and the cuff because they were flat pieces. For this process, boiled water, a bowl and some kitchen cloths were utilized. Firstly, the cuff was modulated with the help of the jig, a 3D printed part, which use was exclusively for this purpose (see Figure 3.5). For the forearm, it was described in the manuals that we needed to use a kitchen roll so that it could have a cylindrical shape.

Figure 3.3: Set of the 3D printed pins.

Figure 3.4: 3D printed fingers and phalanx. On the left side, there is a completed assembled finger - the thumb.

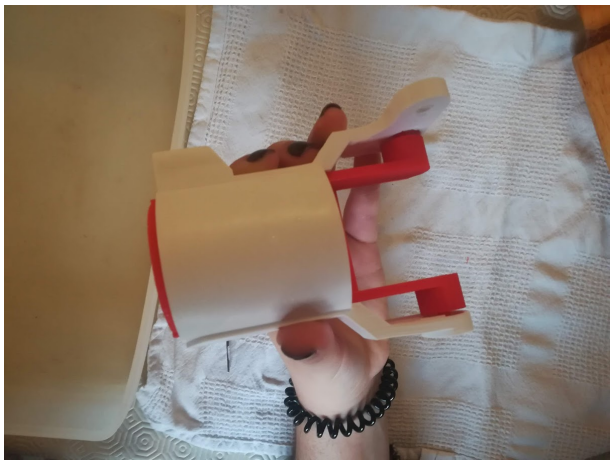


Figure 3.5: 3D printed cuff (white part) fitting the jig (red part).

During the process, there was some trouble regarding the printing process and, for this reason, it was necessary to replace some parts, such as the phalanx (see Figure 3.8). In the first attempt of modulating the forearm, after putting it several times inside boiled water (inclusively inside a pan with boiling water), as shown in Figures 3.6 and 3.7, we found out that the material started to have some slits. Thus, we printed another forearm and used it in the prosthesis.

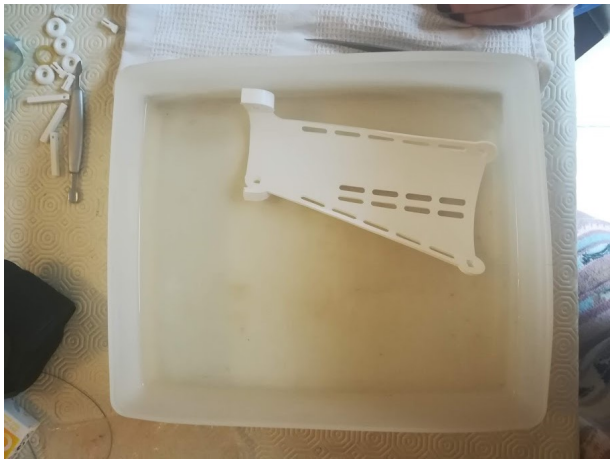


Figure 3.6: 3D printed forearm inside of warm water (around 100°C) to model it.

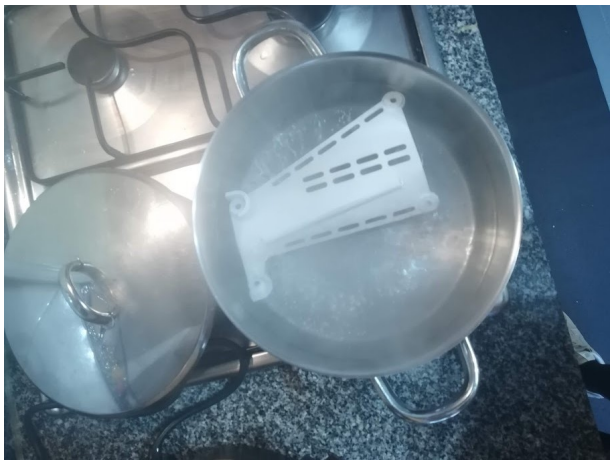


Figure 3.7: 3D printed forearm inside of boiling water (100ºC) in a pan to model it.

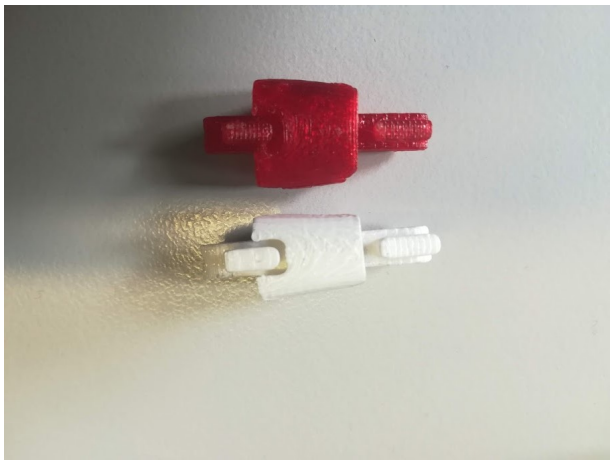


Figure 3.8: Replacement of some white phalanx with red phalanx.

To assemble the device, the pins were used with the help of some springs to keep them in place (see Figure 3.10 and 3.11). The corresponding elbow part was not correctly connected and to solve this situation, a hairdryer was used (see Figure 3.12). In this way, the thermoplastic got softer, enabling the change of its position.

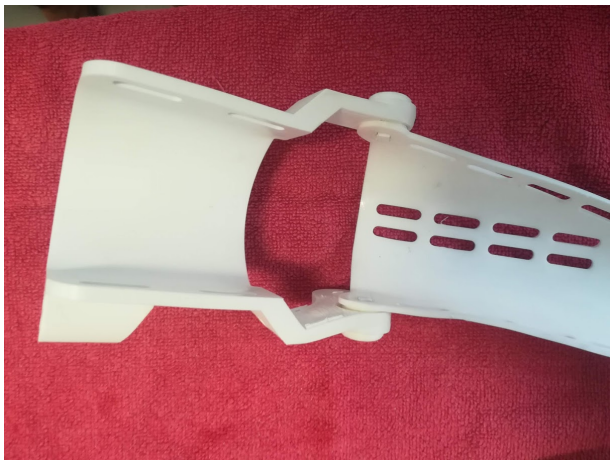


Figure 3.9: Connection mechanism between the forearm and the cuff.

Figure 3.10: Connection mechanism between the forearm and the cuff, by using the pins and a spring to keep them connected.

Figure 3.11: Assembly of the UnLimbited Arm v2.1 - Alfie Edition. The same mechanism was used to connect the hand and the forearm.

Figure 3.12: Heating of the arm by using a hair dryer.

After having the prosthesis completely assembled, we started to place the wire in the right positions. This was carried out having in mind that the wire passed through all the five fingers, as seen in Figures 3.13 and 3.14. We kept the initial length of the wires until the subject tried the prosthesis because some adjustments could have been done. The last step was placing velcro bands in specific holes in the device, having in mind that a bad position could cause scratches in the subject's arm (Figure 3.17).

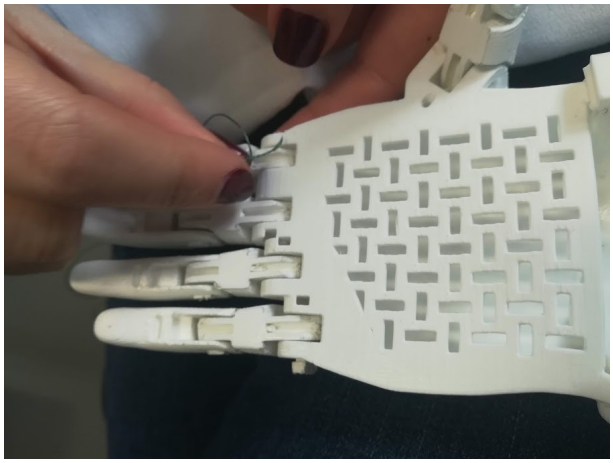


Figure 3.13: Placement of the wire through the holes of the fingers, hand, forearm and cuff.

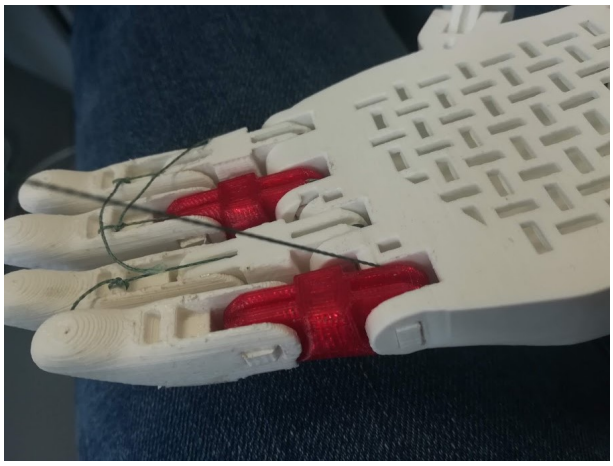


Figure 3.14: UnLimbited Arm v2.1 - Alfie Edition with the wires.

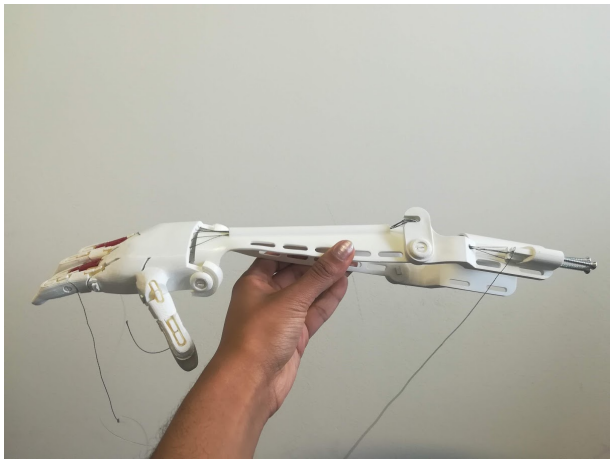


Figure 3.15: Lateral view of the UnLimbited Arm v2.1 - Alfie Edition.

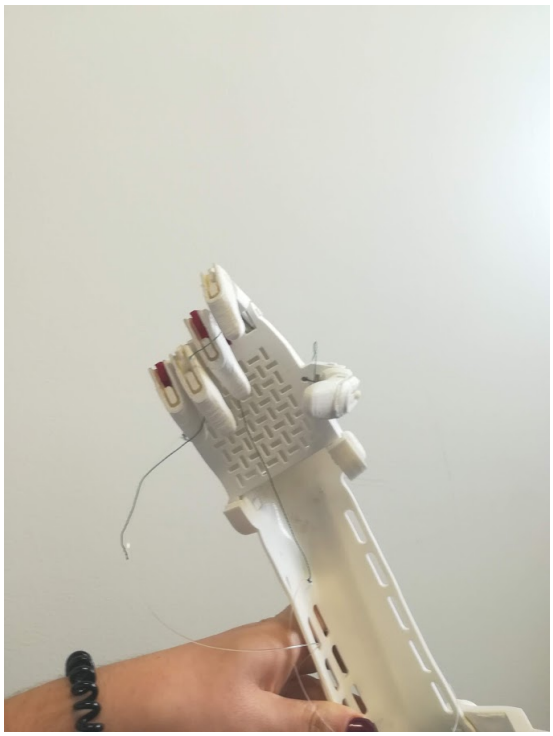


Figure 3.16: Frontal view of the UnLimbited Arm v2.1 - Alfie Edition with the grip closed.

Figure 3.17: Placement of velcro bands in the prosthetic device.

TESTING AND RESULTS

When the subject received the prosthesis, it seemed that he accepted to use it and we had been told that he felt comfortable using it. He tried to grab two objects: an apple and a bottle of water. He was successful completing these tasks, as seen in Figures 3.18 and 3.19.

Figure 3.18: User with the prosthesis holding an apple.

Figure 3.19: User with the prosthesis holding a bottle of water.

Figure 3.20: Lateral view of the prosthetic device in the user's body.

OUTCOME MEASURES

In the process of creating and delivering the prosthesis, we found out that it was necessary to measure the outcome. After PI prostheses deliver, the team was not able to assess the adaptation of the child to the device. In this perspective, a questionnaire was developed to be sent by e-mail to the caregivers, 2 months after the delivery. The questionnaire consisted of three parts:

1. The user's personal data
2. The "Give a Hand" Project
3. The prosthesis function and use

In the first section, the caregiver needed to provide the name, the birth date, gender, birth city and city of residency. In some situations, this was not the first time the subject used a prosthesis. Thus, a non-mandatory field regarding the year of the first use was added. In order to understand how the device fitted in the user's daily life, they were asked the mean number of hours using the prosthesis during the week and during the weekends.

As described in Section 1.3, the "Give a Hand" project main mission is to adapt open-source designs and 3D printed prostheses customized for children (between 3 and 12 years old) who don't have a hand or arm and give it them for free. Regarding the project, it is tremendous important to understand the relevance of the project to the child's well-being. Besides that, by knowing who was the driver of this initiative (parents, the child, health care professional, a friend, another caregiver whose child already had a prosthesis), we could track and understand their motivation. Finally, in this second section, we tried to investigate if another complementary service such as physiotherapy or psychological support would be beneficial to the prosthesis user.

In the last section, the device function and usage were evaluated. Based in the bibliography, the caregiver needed to rate from 0 to 4, 10 different tasks, two measures:

1. MEASURE A: Evaluation of spontaneity of the function of the prosthesis.
2. MEASURE B: Assessment of dexterity of the function of the prosthesis.

Although the detailed explanation of each task can be found in Appendix D, they basically consisted in daily activities such as using a handheld pencil sharpener or peeling a banana. From all the different methods used to measure the outcomes described in Section 2.5.5, the UNB test was chosen because overall, the test was suitable for prosthetic devices, it did not take that long and the amount of tasks was reasonable to perform. On the other hand, this test had different tasks to perform according to the user's age (2-4y, 5-7y, 8-12y and 13-21y). For the case study 1, the tasks were created to the 5-7y age group.

As previously stated, the questionnaire was sent to the caregivers by e-mail. This method is flexible since they could fill in the gaps when they were available. However, in this situation, it did not show promising results. After 2 tries, they did not answer to the e-mail. In my opinion, this is rather because the child is no longer using the device, or they did not find the questionnaire appealing and intuitive enough to fill it in.

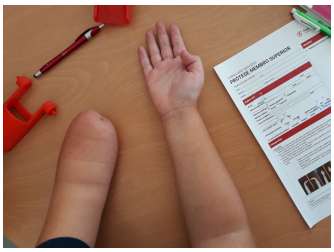
3.2.2 CASE STUDY 2

PATIENT INFORMATION

The second case study was from subject #018. By the time of data collection (October, 2019), he was ten years old and it has been told us that he did not have his left hand due to amniotic band syndrome (see Section 1.2.1). In the following Figures (3.21), we could see the different positions asked in the protocol (see Appendix C, Figure C.2):

(a) Position number 1.

(b) Position number 2.



(c) Position number 3.

Figure 3.21: Three different hand and arm positions, according to the protocol recommendations.

Development and Manufacturing Methods

Just like subject #002, subject #018 needed an elbow actuated e-NABLE arm device - UnLimbited Arm 2.1 (see Figure 2.6a). The process done was very similar to the first device. However, once there was some trouble in the printing process with the printer, we decided to use another printed located at FCT Nova: PrusaSlicer I3 MK3S. The filament was PLA (orange color, as asked by the user).

Regarding the assembling process, the materials used were similar to the ones used in the previous process. Instead of using the braces elastics, another type of elastics was used, as seen in Figure 3.27a. During the process, the 3D printed forearm revealed itself being once again a very difficult part to shape. Figures 3.22 - 3.28 describe the parts needed, as well as the assembling process.

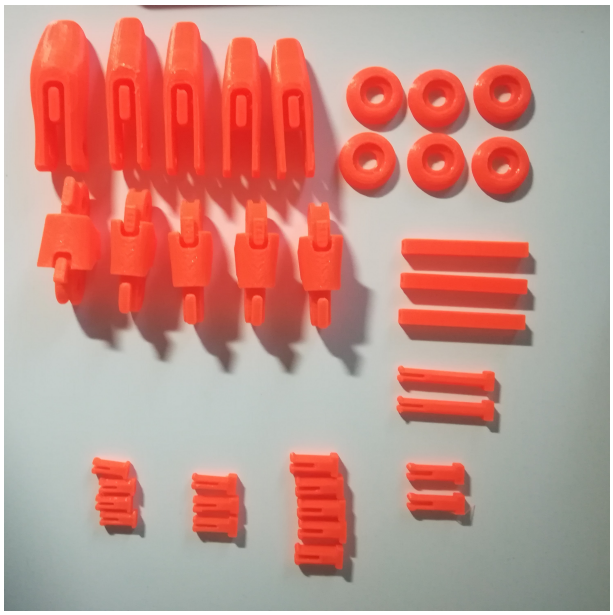


Figure 3.22: Set of the 3D printed pins, fingers an phalanx.

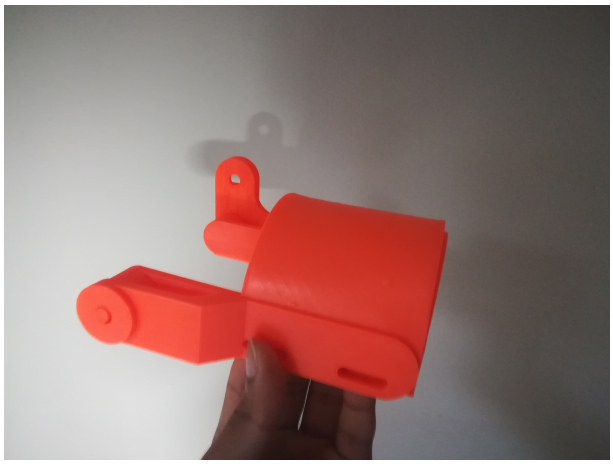


Figure 3.23: 3D printed cuff fitting the jig. Both pieces are orange.

Figure 3.24: 3D printed forearm inside of warm water (around 100°C) to model it.

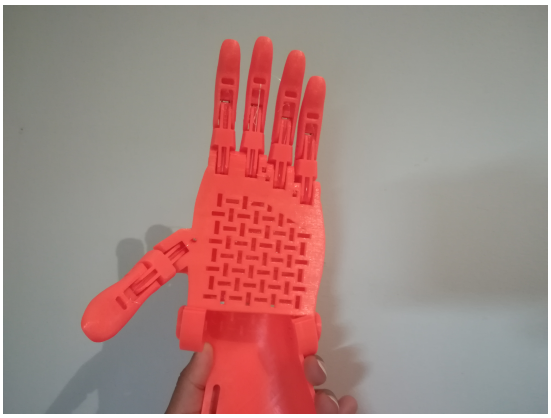
(a) Connection mechanism between the hand and the forearm.

(b) Connection mechanism between the forearm and the cuff.

Figure 3.25: The two connection mechanisms in the arm prosthetic device.

Figure 3.26: The 3D printed hand before being trimmed with the pliers.

(a) Front view of the prosthetic arm (hand).



(b) Back view of the prosthetic arm (hand).

Figure 3.27: Two views of the hand part.

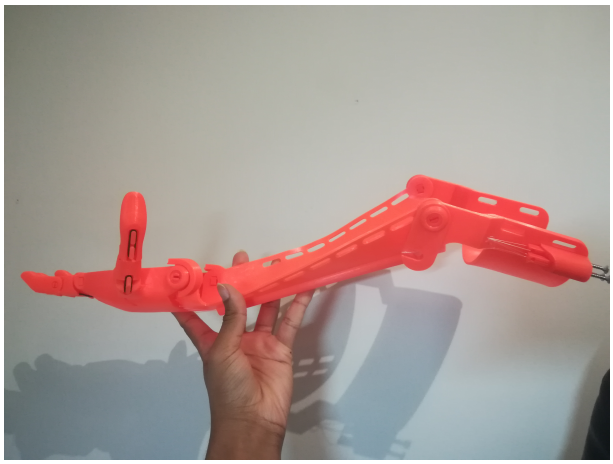


Figure 3.28: Lateral view of the UnLimbited Arm v2.1 - Alfie Edition.

TESTING AND RESULTS

Due to the pandemic situation, it was not possible to test the device next to the user. The device will be delivered afterwards.

OUTCOME MEASURES

Once the user still has not had access to the device, it was not possible to measure the outcomes.

CHAPTER 4

CONCLUSION

4.1 GENERAL CONCLUSIONS

In this work, two upper limb 3D printed prostheses were developed for two different cases studies (5 years old, right hand and 10 years old, left hand).

In order to frame the reason why some kids do not have a part of their upper limb, the introduction addressed the main causes. Congenital limb deficiencies (such as the amniotic band syndrome) were described as the most common cause. Furthermore, there is no treatment for this condition and here arises the need to apply healthcare innovation in these situations.

By analyzing all the prostheses types (passive, electric-powered and body-powered), the first one do not have any function, thus they are not useful in a kid's daily life. Electric-powered devices are sometimes heavy and difficult to handle by kids. They are costly devices and since infants are constantly growing and playing, body-powered prostheses such as the 3D printed ones revealed to be a good option for many families. E-NABLE devices cost around 18 to be developed and can be adapted to each growing stage of the kid. Besides that, they can be printed with different colors, what makes them appealing for infants.

The "Give a Hand" project had a need regarding the outcome measure of the devices after some months of the delivery. An online questionnaire was developed and as a pilot, it was shared with a caregiver by e-mail. However, this did not show promising results. There was no answer from the parents. This might be because the infant was no longer wearing the device, or the parents decided not to fill it in.

Concluding, these 3D printed upper limb prosthetic devices (created by e-NABLE) are affordable and relatively fast to acquire. They can be seen as the first prosthesis of a kid and their main purpose is giving power to the infant to decide, in his/her adult life if he/she would like to have a device.

4.2 FUTURE WORK

There are some improvements and future work that would be beneficial to add to this project. In the online survey, there was a section regarding the psychological and physiotherapy support to the prosthesis user. Although there are no data in this work supporting it, in the future, PI should analyze the hypothesis of establishing partnerships with clinics to provide this service to infants. In this way, this would decrease the drop-outs and improve the user experience.

Secondly, growth of infants is seen as an obstacle in the development of prostheses. This is because it is difficult to predict how much the infant will grow until he/she has the device. In the future, an algorithm able to predict the growth would improve this challenge.

Finally, e-NABLE devices work for kids without any fingers and whose stub is thin. A service able to modify the model with CAD Softwares would be beneficial to have a wider range of devices.

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APPENDIX A

CLASSIFICATION OF CONGENITAL SKELETAL LIMB DEFICIENCIES

Terminal (T)[9]

Transverse (-)

1. Amelia (absence of limb)
2. Hemimelia (absence of forearm and hand or leg and foot)
3. Partial hemimelia (part of forearm or leg is present)
4. Acheiria or apodia (absence of hand or foot)
5. Complete adactylia (absence of all five digits and their metacarpals or metatarsals)
6. Complete aphalangia (absence of one or more phalanges from all five digits)

Longitudinal (/)

1. Complete paraxial hemimelia (complete absence of one of the forearm or leg elements, and of the corresponding portion of the hand or foot)
2. Incomplete paraxial hemimelia (similar to the above, but part of the defective element is present)
3. Partial adactylia (absence of one to four digits and their metacarpals or metatarsals)
4. Partial aphalangia (absence of one or more phalanges from one to four digits)

Intercalary (I)[9]

Transverse (-)

1. Complete phocomelia (hand or foot attached directly to trunk)
2. Proximal phocomelia (hand and forearm, or foot and leg, attached directly to trunk)
3. Distal phocomelia (hand or foot attached directly to arm or thigh)

Longitudinal (/)

1. Complete paraxial hemimelia (similar to corresponding terminal defect but hand or foot is more or less complete)
2. Incomplete paraxial hemimelia (similar to corresponding terminal defect but hand or foot is more or less complete)
3. Partial adactylia (absence of all or part of a metacarpal or metatarsal)
4. Partial aphalangia (absence of proximal or middle phalanx, or both, from one or more digits)

APPENDIX B

THE UPPER-EXTREMITY RESIDUAL LIMB

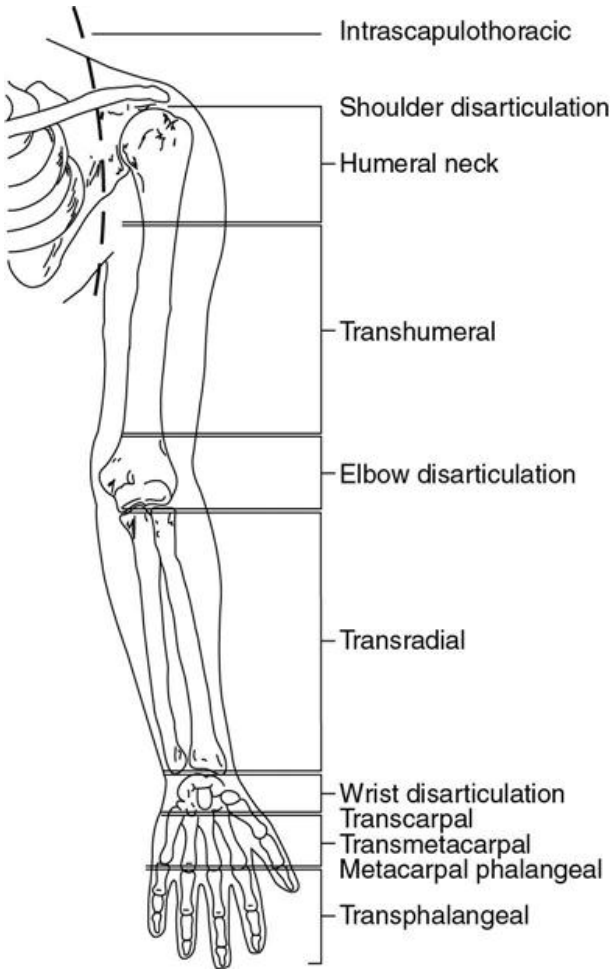
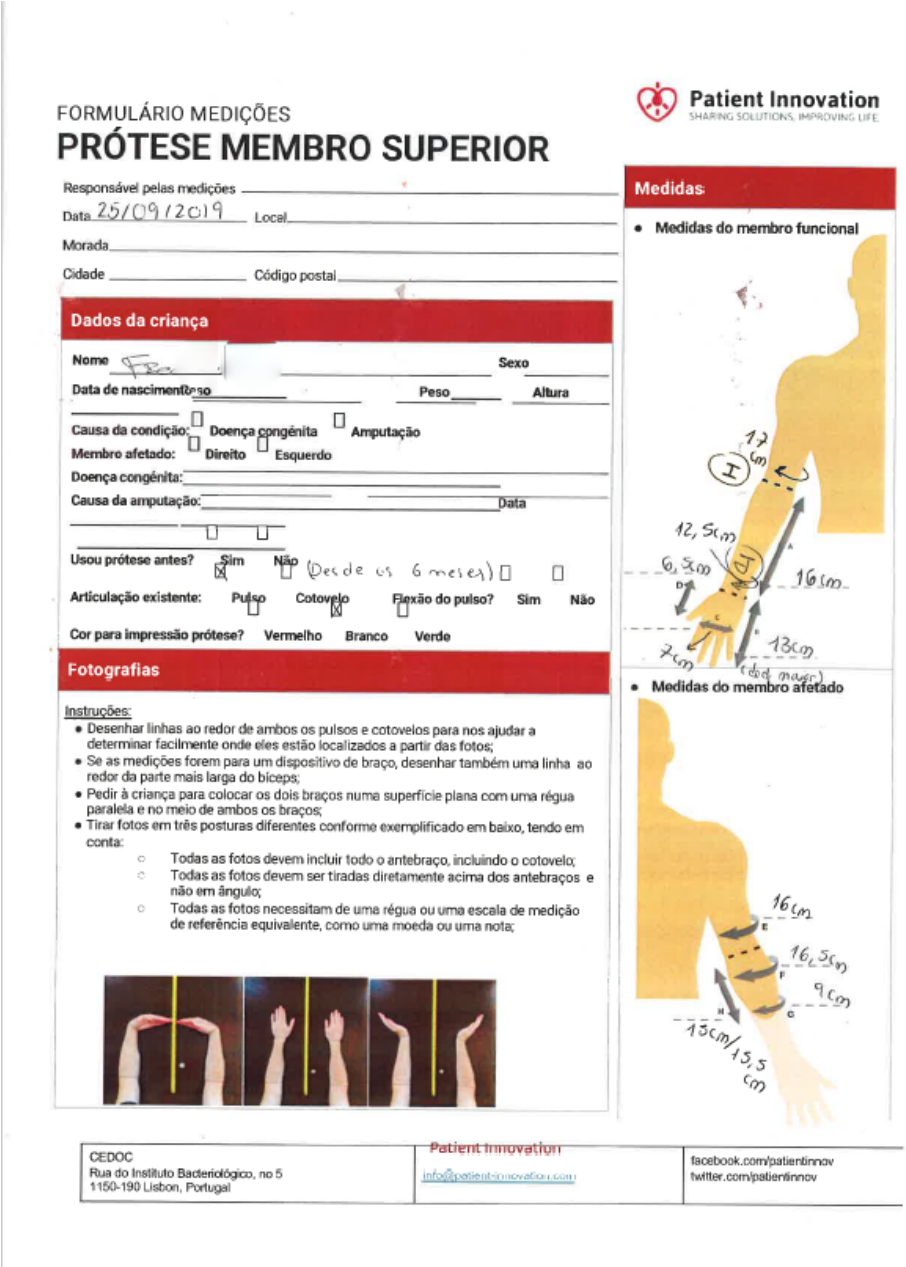


Figure B.1: The upper-extremity residual limb described by the bony limb segment at which amputation occurred [64]

APPENDIX C

PROTOCOLS



FORMULÁRIO MEDIÇÕES

PRÓTESE MEMBRO SUPERIOR

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Responsável pelas medições _____

Data 25/09/2019 Local _____

Morada _____

Cidade _____ Código postal _____

Dados da criança

Nome _____ Sexo _____

Data de nascimento _____ Peso _____ Altura _____

Causa da condição: ☐ Doença congénita ☐ Amputação

Membro afetado: ☐ Direito ☐ Esquerdo

Doença congénita: _____

Causa da amputação: _____ Data _____

Usou prótese antes? Sim ☒ Não ☐ (Desde os 6 meses) ☐ ☐

Articulação existente: Pulso ☐ Cotovelo ☒ Flexão do pulso? Sim ☐ Não ☐

Cor para impressão prótese? Vermelho ☐ Branco ☐ Verde ☐

Fotografias

Instruções:

- Desenhar linhas ao redor de ambos os pulsos e cotovelos para nos ajudar a determinar facilmente onde eles estão localizados a partir das fotos;
- Se as medições forem para um dispositivo de braço, desenhar também uma linha ao redor da parte mais larga do bíceps;
- Pedir à criança para colocar os dois braços numa superfície plana com uma régua paralela e no meio de ambos os braços;
- Tirar fotos em três posturas diferentes conforme exemplificado em baixo, tendo em conta:
  - Todas as fotos devem incluir todo o antebraço, incluindo o cotovelo;
  - Todas as fotos devem ser tiradas diretamente acima dos antebraços e não em ângulo;
  - Todas as fotos necessitam de uma régua ou uma escala de medição de referência equivalente, como uma moeda ou uma nota;

Medidas

- Medidas do membro funcional

- Medidas do membro afetado

CEDOC
Rua do Instituto Bacteriológico, no 5
1150-190 Lisbon, Portugal

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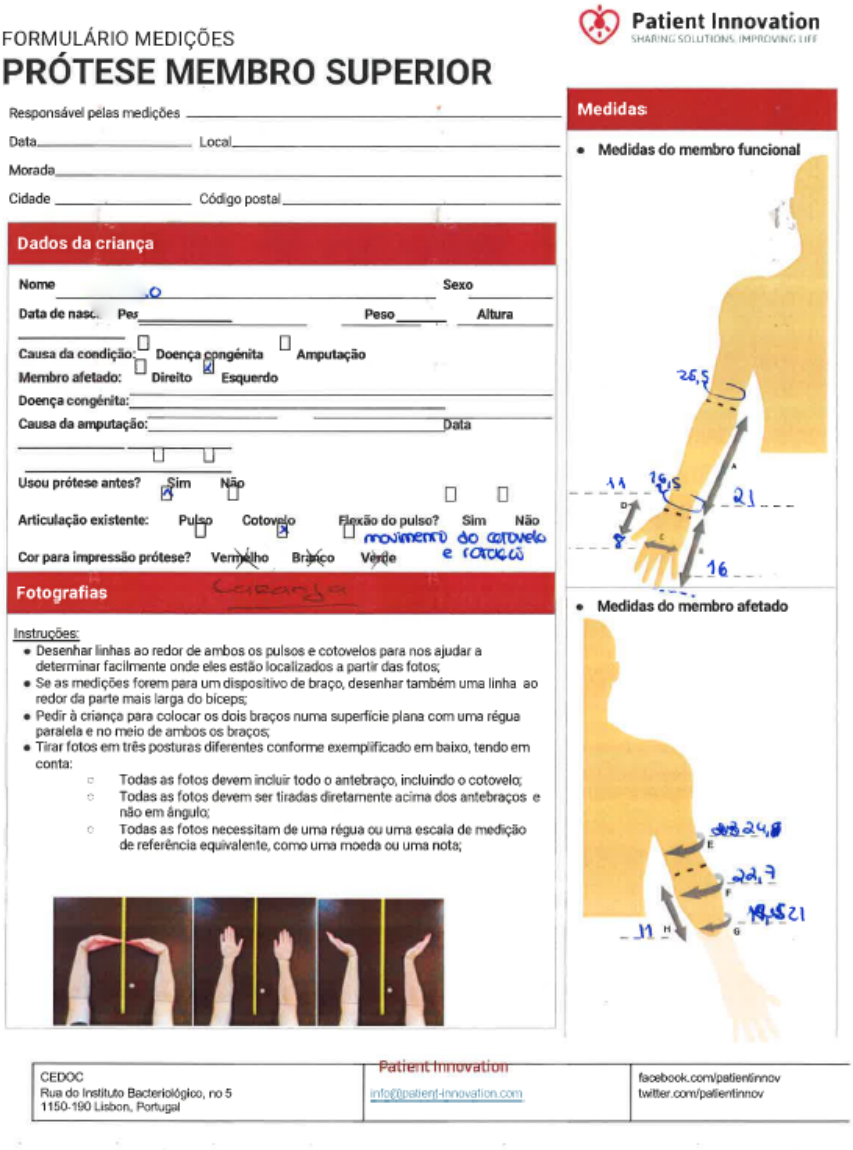
Figure C.1: Filled protocol of case study 1.



FORMULÁRIO MEDIÇÕES

PRÓTESE MEMBRO SUPERIOR

Patient Innovation
SHARING SOLUTIONS, IMPROVING LIFE

Responsável pelas medições

Data Local

Morada

Cidade Código postal

Dados da criança

Nome Sexo

Data de nasc. Pes Peso Altura

Causa da condição: Doença congénita Amputação

Membro afetado: Direito Esquerdo

Doença congénita:

Causa da amputação: Data

Usou prótese antes? Sim Não

Articulação existente: Pulso Cotovelo Flexão do pulso? Sim Não

movimento do cotovelo e rotação

Cor para impressão prótese? Vermelho Branco Verde

Fotografias

Instruções:

- Desenhar linhas ao redor de ambos os pulsos e cotovelos para nos ajudar a determinar facilmente onde eles estão localizados a partir das fotos;
- Se as medições forem para um dispositivo de braço, desenhar também uma linha ao redor da parte mais larga do bíceps;
- Pedir à criança para colocar os dois braços numa superfície plana com uma régua paralela e no meio de ambos os braços;
- Tirar fotos em três posturas diferentes conforme exemplificado em baixo, tendo em conta:
  - Todas as fotos devem incluir todo o antebraço, incluindo o cotovelo;
  - Todas as fotos devem ser tiradas diretamente acima dos antebraços e não em ângulo;
  - Todas as fotos necessitam de uma régua ou uma escala de medição de referência equivalente, como uma moeda ou uma nota;

Medidas

- Medidas do membro funcional

- Medidas do membro afetado

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Rua do Instituto Bacteriológico, no 5
1150-190 Lisbon, Portugal

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Figure C.2: Filled protocol of case study 2.

APPENDIX D

TASKS: QUESTIONNAIRE FOR OUTCOMES MEASURES

ESCALA A	
Avaliação da espontaneidade da função da prótese	**Pontuação**
Utilização imediata, automática e consistente da prótese para agarrar.	4
Ligeiro atraso ou utilização não consistente da prótese para agarrar.	3
Utilização ocasional, com um grande atraso e apenas em último recurso.	2
Utilização da prótese como equipamento terminal apenas.	1
Prótese não utilizada ou apenas usada se for solicitado.	0

ESCALA B	
Avaliação da destreza da função da prótese	**Pontuação**
Utilização ativa, rápida e suave da prótese e o mecanismo de agarrar é consistente.	4
A utilização da prótese demonstra alguma lentidão, incerteza. O mecanismo de agarrar é rapidamente restaurado.	3
É tentada uma utilização ativa da prótese, mas esta é muito lenta. A função de agarrar é muitas vezes perdida ou recuperada com dificuldade.	2
Sem função ativa da prótese, apesar de algumas partes dela poderem ser usadas passivamente para estabilizar ou dar suporte.	1
A prótese não é utilizada.	0

Figure D.1: The two measures used in the questionnaire for outcome measures.

Figure D.2: The ten tasks the prosthesis user needed to perform while filling the online questionnaire.